December 20, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 99N-4491, FDA's Proposed Strategy on Reuse of Single Use Devices (64 *Federal Register* 59782), November 3, 1999

Ladies and Gentlemen:

The American Hospital Association (AHA), representing nearly 5,000 hospitals, health networks and other providers of care, as well as more than 39,000 personal members, appreciates the opportunity to comment on the Food and Drug Administration's (FDA) proposed strategy to address the reuse of medical devices currently labeled, or otherwise intended, for only one use (Proposed Strategy). The AHA is encouraged by FDA's decision to act in this area to ensure and enhance patient safety, which is the first and foremost concern of the AHA's members.

As providers of health care, our members have experience with reprocessed medical devices and are eager to work with the FDA as it refines its oversight of reused and reprocessed medical devices. In particular, the American Society for Healthcare Central Service Professionals (ASHCSP), an AHA personal membership group, and its members, have been pioneers in developing safe and effective techniques for reprocessing devices, and have been proactively addressing the issues that form the basis for the FDA's Proposed Strategy for many years. We are pleased to participate in this dialogue.

The Proposed Strategy represents a thoughtful approach to a complex issue; it both echoes and furthers the goals of patient safety, which we share. Further, we recognize that this proposal represents the FDA's first step in developing a more detailed strategy for single use devices (SUDs). For instance, FDA does not set out specific criteria for how the agency would categorize devices and, as a result, its proposal with respect to categorization is incomplete. As such, it is difficult for the AHA to definitively assess the strategy and its impact on health care facilities.

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We plan to continue to work closely and cooperatively with the FDA and other stakeholders as more details of its strategy are developed. In order to ensure the most benefit from this interaction, we strongly encourage the FDA to identify all of the issues that bear on the Proposed Strategy and vet its proposals before any are implemented.

Further Research Should Be Conducted Regarding the Safety of Reprocessing

Device malfunctions, patient injuries, or infections relating to the reprocessing and reuse of single-use devices (SUDs) are a matter of concern. At present, however, it is clear that the medical, reprocessing and original equipment manufacturer (OEM) communities lack sufficient information to properly assess this issue.

Indeed, in response to a recent citizen's petition filed by the Medical Device Manufacturers Association requesting that re-used medical devices be banned, the FDA concluded: "In fact, FDA has been unable to find clear evidence of adverse patient outcomes associated with the reuse of a single use device from any source. Therefore, the 'unreasonable and substantial risk' criterion has not been met." (Letter to Larry R. Pilot, Esq., October 6, 1999.) One year earlier, the FDA denied a similar citizen's petition from the Health Industry Manufacturer's Association, citing, among other things, a lack of evidence of adverse outcomes. At that time, the FDA specifically encouraged "trade and scientific organizations, OEMs, user facilities, and others, to provide any data demonstrating adverse patient outcomes from the use of reprocessed 'single use only' devices," but noted that as of that time, FDA had seen "no documented evidence that the treatment of patients with, or other patient use of, these reprocessed devices has caused adverse clinical outcomes." (Letter to Nancy Singer, Esq., July 13, 1998.) Further, the FDA should assume that it would have been informed of any significant problems from reprocessed SUDs under the Safe Medical Devices Act' mandatory Medical Device Reporting (MDR) regulation, or the voluntary MEDWATCH program. Both programs are taken very seriously by health care facilities.

After many years of experience with reprocessed SUDs and despite a significant period of study and specific requests from FDA and others to be informed of the details relating to problems with reprocessed SUDs, the health care field has not yet seen evidence of a significant problem. As such, it is incumbent upon us, as clinical practitioners and scientists, to conduct further research.

The FDA expresses interest in pursuing a research program that focuses on the reuse of SUDs and invites collaboration by interested parties. The AHA strongly supports such a research program, to help bridge the data gap that exists between the perceived and actual safety risks associated with reuse of SUDs. To ensure that research dollars are used most cost-effectively, we recommend that such research be directed at the more complex or high-

risk devices. Finally, we believe that in order to be meaningful and credible, all such research should be peer reviewed and published. The AHA would be pleased to assist in the dissemination of research results.

Development and Application of Consensus Standards

Item 6 of the Proposed Strategy is intended to explore the possible use of consensus standards on a device-specific basis for reprocessed SUDs. The AHA believes that consensus standards play an important role in regulating industry conduct, regardless of whether they form the basis of compliance with specific FDA requirements, such as premarket notification.

In developing a consensus standard program for reprocessing SUDs, the FDA should carefully consider revising the process through which such consensus standards have historically been developed. As the FDA's experience with the development of consensus standards to date will surely confirm, the process by which a consensus standard is developed by an organization, such as American National Standards Institute (ANSI) or the Association for the Advancement of Medical Instrumentation (AAMI), and recognized by the FDA is lengthy. The FDA should also consider whether the traditional standard development organizations, which historically have been geared to the needs of OEMs, are the best parties to facilitate the development of reprocessing standards. Since health care facilities, physicians, and third-party reprocessing firms are also involved in reprocessing activities, the FDA should bring these stakeholders into the process for developing consensus standards.

The reprocessing of SUDs is a complex issue, with the levels of risk dependent upon a number of factors such as the way the device has been treated, the infection control status of the device and its physical characteristics, and the risk associated with device failure. To ensure a rational and expeditious process, the AHA believes that the process for developing consensus standards should depend upon the risk categorization of the device or class of devices.

For low risk devices, we would support developing consensus standards that use a "community best practices" model. Such best practices should be developed by professional associations, including physician specialty societies, sterile processing professionals, infection control professionals, and reprocessors. Although such a structure does not currently exist, the AHA would be willing to take a leadership role in such a "community best practices" process that could be used to develop consensus standards for lower risk devices.

For higher risk devices, the FDA should consider the creation of an interdisciplinary advisory panel of health care professionals (infection control, physicians, sterile processing professionals) and device manufacturers to lead this effort. If the agency starts such a program, the AHA is committed to active participation and can offer the expertise of the medical experts within its membership to assist in the effort.

Regardless of who develops the standards, however, given the large number of reprocessed devices that would require standards, it is doubtful that device-specific consensus standards could be developed quickly enough to allow reprocessors to effectively utilize the standards as a cost saving measure in sufficient time to make it economically worthwhile from a business point of view. To the extent that regulatory burdens cause reprocessors to exit the business, the overall impact on health care costs could be enormous. It may be possible to classify similar devices into categories to permit the development of fewer consensus standards -- each of which would cover a larger range of devices.

Health Care Facilities and Existing Oversight Authority

To the extent that the Proposed Strategy deals with "establishments that reprocess SUDs," it should distinguish between health care facilities that engage in reprocessing, and third-party reprocessors. The FDA's Proposed Strategy sets out to treat both groups in the same manner as it has regulated OEMs. The AHA believes that there are meaningful differences between health care facilities and third-party reprocessors and that those differences should be recognized by the FDA.

First, health care facilities are already subject to significant regulatory and accreditation oversight by entities such as HCFA, the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), state licensing authorities, and other county and city agencies, particularly as with respect to patient safety and quality of care. By contrast, third-party reprocessors have no such existing source of outside regulation. Indeed, the FDA has recognized, in the Proposed Strategy, that a decision to regulate health care facilities may require collaboration with "accredited third-party organizations or other federal agencies" (Proposed Strategy at Section 1).

Second, the activities of health care facilities are marked by a high degree of physician involvement, supervision and control. In many cases, the reprocessing activities of health care facilities are overseen by a multi-disciplinary committee, consisting of clinical (e.g., physicians, nurses) and operational staff, authorized by the medical staff. This committee is responsible for monitoring reprocessing quality assurance and improvement activities, recommending strategies for improving performance, and reporting such findings and recommendations to the facility's performance improvement oversight committee, medical staff and governing body. Through its membership, activities and reporting structure, this multi-disciplinary committee meets the requirements of numerous JCAHO standards, including those in the chapters on Surveillance, Prevention and Control of Infection, Leadership, Improving Organization Performance, and Governance. Naturally, medical professionals and the health care facilities in which they practice have quality patient care as their primary mission and have in place standards, policies and procedures for reprocessing.

These standards, policies and procedures, in conjunction with the quality improvement program, are designed specifically to protect the well-being of their patients. Existing non-FDA regulatory oversight, which the AHA believes includes the components necessary to address and satisfy the FDA's concerns in this area, has resulted in the development of these processes. In fact, in many respects, the existing oversight is substantially equivalent to what the FDA appears to be considering with respect to the registration, inspection, and quality system regulation requirements for health care facilities. For instance, JCAHO, during its announced and unannounced surveys, focuses heavily on patient safety issues. In addition to visits to patient care areas and reprocessing areas to observe infection control practices, JCAHO reviews the minutes of the infection control committee, the medical staff executive committee, the performance improvement oversight committee and the governing body for evidence of sufficient reporting of performance improvement information and for action on performance improvement recommendations. Failure to adequately demonstrate compliance in these areas would result in substantial findings of non-compliance for the facility.

Third, hospitals and health care facilities are not engaged in any form of interstate commerce, their services do not cross state lines, and they are not in the business of manufacturing or distributing products. As such, they are generally not considered to be within the scope of the FDA's regulatory mandate. The FDA recognized as much when it established its policy with respect to reprocessing by health care facilities, as expressed in Compliance Policy Guide (CPG) 300.500, which, for over 20 years, has placed responsibility for hospitals' reprocessing and reuse of SUDs with the hospitals, without any FDA oversight or affirmative regulatory requirements (such as registration, listing, inspections, premarket notification or approval, and other such requirements).

Finally, the FDA has affirmatively refused to take various regulatory actions that might result in regulating the practice of medicine, a power that is widely considered to have been reserved to state and local authorities. Importantly, some of the reprocessing activities undertaken by health care facilities involve a separate category that bears little resemblance to the activities of third-party reprocessors. This category of reprocessing is not part of a centralized "assembly-line" operation, as one would expect to find at a third-party reprocessor, but is performed by clinical personnel working in a clinical area, such as a Cardiac Catherization Lab, processing device by device (angioplasty balloon catheters, cardiac catheters and guidewires, etc.) under the supervision of a physician in connection with a specific medical procedure. The physician leaders of these clinical areas are responsible for the activities and performance of all staff within such functional units. AHA believes that this category of specialized reprocessing activities has been, and should continue to be, within the scope of the practice of medicine and should therefore not be subject to regulation in any way.

Additional regulatory guidance must consider the high level of external regulatory and other oversight and internal controls to which health care facilities are already subject. The AHA is prepared to engage with FDA in a discussion of whether and in what way existing quality control procedures fail to address quality assurance and patient safety goals.

The Use of Enforcement Discretion

The FDA has proposed, through its use of "enforcement discretion," that reprocessors of SUDs not be required to file premarket notification submissions (510(k)s) for reprocessed SUDs if the products fall within the proposed classification scheme as "low-risk" devices and meet certain other requirements. (The policy would also extend to "moderate-risk" devices for a period of two years.) The AHA concurs with the FDA's position that 510(k) submissions are not necessary for such devices and believes the rationale behind it is sound. Devices that pose little or no public health risk to patients or users after reprocessing should have minimal, if any, regulatory requirements, including premarket filings.

We are concerned, however, that the Proposed Strategy, as presented, fails to make clear for the public, health care facilities, and other regulators who rely on the FDA's expertise in this area, that it is the FDA's judgment that reprocessing and reuse of such devices is acceptable from a regulatory and compliance standpoint. It is important that on issues of safety and efficacy there be clarity about the FDA's views.

We understand that the Proposed Strategy is a first step in the guidance process. We urge the FDA to take whatever further steps are necessary, including regulatory or legislative action beyond the issuance of guidance documents, to provide the requisite clarity.

Regulating the Use of "For Single Use Only" Labeling

Reprocessing has historically allowed health care facilities to treat a greater number of patients and achieve cost savings without sacrificing patient safety. The AHA believes that a balance can be struck that upholds the essential goal of safety, while minimizing regulatory burdens that might unduly strain the resources of health care providers. Part of the reason that health care providers experience such a strain is the recent proliferation of costly SUDs and the demise of many reusable products. The fact is that OEMs have very little incentive to label new devices as reusable. Doing so requires them to conduct extra testing and subjects them to additional legal liability. In addition, the FDA does not require OEMs to justify the labeling of products as "single use only."

The AHA strongly supports the initiative outlined in Item 4 of the Proposed Strategy, which calls for an examination of whether OEMs should be required to label SUDs with information about the risks associated with reuse. The FDA should ensure that such labeling is premised upon a body of scientific evidence setting out the quantifiable risk associated with the resterilization, reprocessing or reuse of each particular device. In addition, we would go one step further: to the extent that OEMs have already developed safe and effective reprocessing techniques for their SUDs, they should be required to add such instructions to the labeling of the devices.

We are concerned that under current regulations, OEMs are permitted to use the terms "single use only" as part of their labeling without justifying whether, in fact, the device is capable of reprocessing for subsequent uses. Thus, the FDA should consider a more objective and evidence-based approach to the labeling of these devices. For example, if the OEM has developed device-specific data to show that sterilization by steam autoclave will harm the integrity of the device, the labeling could read "do not sterilize by steam autoclave." Permitting the OEM to use the "single use only" designation in such an instance would be overly broad if other methods of sterilization were available that did not harm the integrity of the device. These decisions would most appropriately be addressed during the 510(k) or premarket approval process.

Such requirements would be appropriate because OEMs, not reprocessors, have a defined expertise with regard to their devices. While reprocessors necessarily lack the design data, specifications, and knowledge of tolerances and parameters for device performance, the OEMs are the source for such data. As such, they are in a unique position to predesign and establish instructions for reprocessing and reuse.

FDA should regulate the use of the "single use only" label and require OEMs to specify any resterilization or reprocessing techniques that compromise the integrity of the device. Such labeling must be premised upon a body of scientific evidence setting out the quantifiable risk associated with the resterilization, reprocessing or reuse of the particular device. The meaningful use of the "single use only" contraindication should be restricted to only those circumstances in which an OEM has demonstrated to the FDA that no resterilization, reprocessing, or reuse can safely occur.

Reprocessing of Opened But Unused SUDs Deserves Special Treatment

The Proposed Strategy has created a definition of opened but unused single use device as "a device whose sterility has been breached or whose sterile package was opened but the device has not been used on a patient". The AHA believes that these devices should be treated differently from other reprocessed SUDs, for several reasons.

As noted above, the AHA is aware of little, if any, evidence to demonstrate a significant, let alone pervasive, problem with reprocessed SUDs. Furthermore, we are aware of no scientific evidence pointing to a problem with the reprocessing of opened but unused devices. In fact, the reprocessing of these devices does not raise the same level of concern as the reprocessing of devices that have been used on a patient, because, by definition, they have not been used.

To explain this issue, it appears that there are three general areas of risk associated with reprocessing activities: (1) contamination of the device, if it is not properly cleaned and sterilized, could lead to infection; (2) the cleaning and/or sterilization process could harm the integrity of the device; and (3) the repeated use of the device in subsequent procedures could harm the integrity of the device. With respect to unused devices, the third risk is eliminated entirely. A major component of the first risk, patient cross-contamination, is also eliminated. The only possible risks, therefore, are whether the device can be adequately resterilized and if the process of resterilization somehow harms the device. In order for these issues to be resolved, scientific analysis and technological expertise, that are beyond the scope of this letter, are needed. Health care facilities have a great deal of experience in sterilization of medical devices as sterilization is routinely performed on many types of devices. In fact, as reported to the AHA, it is not uncommon for OEMs to ship SUDs to health care facilities with separate sterilization instructions, if the OEM is experiencing a period of high demand and has not had the time to sterilize the SUDs prior to shipment. Thus, it is not clear to the AHA that the "single use only" label and "do not resterilize" instructions are premised upon any reliable body of scientific evidence.

One specific concern raised by AHA members is the fact that many single-use devices are routinely opened prior to use and assembled as part of customized procedure trays that contain many devices. Sterile processing professionals assemble, wrap and sterilize these trays, which may consist of both single-use and disposable items. It is essential that health care facilities be permitted to open single-use devices, combine them with other devices in the way that suits their practice of medicine, and resterilize the entire tray, without treating the operation as a "reprocessing" activity. In fact, the creation of these trays in advance of surgeries and other procedures is designed to avoid delays in the surgical suite and prevent subsequent infection during the procedure.

The FDA should exempt reprocessing of opened but unused SUDs (including, but not limited to customized procedure trays, as described above, and other physician-directed and patient- specific uses of SUDs) and simple resterilization from any new policy that the FDA develops.

Device Categorization

The AHA agrees that categorization of SUDs into risk categories is an appropriate step in regulating reprocessing activities. The AHA's personal membership group of central services professionals, ASHCSP, had been considering this very categorization issue long before the Proposed Strategy was issued and has developed a "matrix" for determining and categorizing risk which takes into account the following elements: (1) device treatment; (2) "infection control" status; (3) physical characteristics of the device; and (4) risk to patient should the device fail. The dimensions of the matrix are described below.

1. Device Treatment

(a) Reuse: the cleaning, packaging and sterilization of a single-use medical device after use on a patient for the intended purpose of using it on another patient.
(b) Reprocessing: the packaging and sterilization of a device that has been opened, but not used on a patient.
(c) Resterilization: the sterilization of an unopened sterile device placed inside a pack or tray along with other devices. This would also apply for dated items where the expiration date does not relate to product deterioration or drug potency.

2. "Infection Control" Status

(a) Critical: a device that will penetrate a sterile tissue plane during use, i.e., invasive devices for diagnostic purposes, implantable devices or components of heart-lung oxygenator.
(b) Semi-critical: a device that will not penetrate a sterile tissue plane, but will touch or enter mucous membrane during use, i.e.. breathing circuits and other respiratory devices and endoscopes.
(c) Non-critical: a device that will not penetrate a sterile tissue plane or mucous membrane during use, but may touch the patient's intact skin, i.e., blood pressure cuffs, oxygen masks, skin staple removers and restraints.

3. Physical Characteristics of Device

(a) Multi-channel
(b) Optic fibers
Lumen size < 2mm
Lumen size > 2mm
Lumen length < 17cm
Lumen length > 17cm

(c) Device composition
(d) Multi-interlocking components
(e) Surface texture (smooth, etc.)
(f) Functional purpose of device (sharpness, etc.)

4. Risk to Patient

(a) Device failure has potential to cause serious injury or death
(b) Device failure has potential to delay the procedure or treatment.
(c) Treatment increases risk of infection.
(d) No risk to patient.

The AHA believes the FDA should consider the dimensions of this matrix as it develops the criteria upon which to base its risk categorization scheme. Further, we recommend that the level of regulation applied to a particular device not only take into account other safety and quality-related regulation of the entity doing the reprocessing but also correspond to the level of risk to a patient for that device. For products that bear a low likelihood for risk to the patient, regulatory burdens should be minimal.

The List of Frequently Reprocessed SUDs Should Be Supplemented

AHA believes that the List of Frequently Reprocessed SUDs is incomplete and the FDA should consider supplementing the list with at least the devices listed below, and perhaps others. We note that some of the classifications, for example, saw blades and drills, are devices that are sometimes sold labeled for single use and sometimes sold with sterilization instructions. As noted above, AHA urges the FDA to seek uniformity from OEMs in the way that they label such devices. In any event, the final list of frequently reprocessed devices should fully and fairly represent the input of the entire reprocessing community including health care facilities, health care practitioners, third-party reprocessors and OEMs. Based on the input of AHA and ASHCSP members, we recommend that the FDA add the following devices to the list of frequently reprocessed SUDs:

Angioplasty Balloon Catheters
Aortic Punches
Arthroscopic Bone Shavers
Biopsy Needles
Blood Pressure Cuffs
Breathing Circuits
Cardiac Catheters
Cardiac Guide Wires
Carpel Tunnel Blades
Electrophysiology Catheters

Electrosurgical Electrodes
Endo Carpal Tunnel Blades
Endotracheal Tubes
External Fixation Device
Fascia Holders
Femostop
GI Biopsy Forceps
High Speed Cutters (Midex Rex, etc.)
Keratome Blades
Laparoscopic Dissectors
Laparoscopic Graspers
Laparoscopic Scissors
Lap Choly CannulaTrocar
Laser Fibers -- YAG
Opthalmic Probe
Orthodontic Braces
Plastic Connectors
Pulse Oximeter Sensors
Reamers
Scissor Tips, Removable Inserts
Sequential Compression Device Sleeves
Staplers
Surgical Burrs
Surgical Drill Bits
Surgical Saw Blades
Sutures
Trocars
Uterine Manipulator

In addition, the following list, although not exhaustive, represents the typical kinds of devices included in customized procedure trays which are opened, assembled, wrapped and sterilized by sterile processing professionals for use in surgeries and other procedures:

Drapes (Paper)
Needles
Scalpels
Sponges
Stopcocks
Syringes

Again, the AHA appreciates the opportunity to comment and to participate in the dialogue among the FDA and interested stakeholders. Specifically, we would appreciate an opportunity to respond in detail to other comments that the FDA receives. The AHA also reserves the right to comment further, as the policy evolves. If you have questions regarding these comments, feel free to call me, Carmela Coyle, senior vice president for policy, at (202) 626-2266, or Roslyne Schulman, senior associate director for policy development, at (202) 626-2273.

Sincerely,

Rick Pollack

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Executive Vice President

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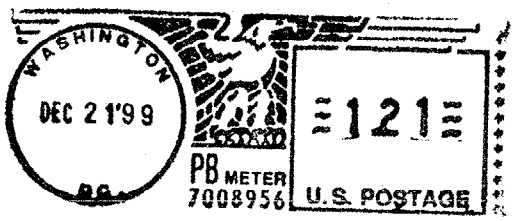

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